

§ 1.790

within the period for reply set shall be regarded as conclusively establishing that the applicant is not the holder of the regulatory approval.

(e) Determinations made under this section shall be included in the notice of final determination of eligibility for extension of the patent term pursuant to §1.750 and shall be regarded as part of that determination.

[60 FR 25618, May 12, 1995, as amended at 62 FR 53201, Oct. 10, 1997]

§ 1.790 Interim extension of patent term under 35 U.S.C. 156(d)(5).

(a) An owner of record of a patent or its agent who reasonably expects that the applicable regulatory review period described in paragraph (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii) of subsection (g) that began for a product that is the subject of such patent may extend beyond the expiration of the patent term in effect may submit one or more applications for interim extensions for periods of up to one year each. The initial application for interim extension must be filed during the period beginning 6 months and ending 15 days before the patent term is due to expire. Each subsequent application for interim extension must be filed during the period beginning 60 days before and ending 30 days before the expiration of the preceding interim extension. In no event will the interim extensions granted under this section be longer than the maximum period of extension to which the applicant would be entitled under 35 U.S.C. 156(c).

(b) A complete application for interim extension under this section shall include all of the information required for a formal application under §1.740 and a complete application under §1.741. Sections (a)(1), (a)(2), (a)(4), and (a)(6)–(a)(17) of §1.740 and §1.741 shall be read in the context of a product currently undergoing regulatory review. Sections (a)(3) and (a)(5) of §1.740 are not applicable to an application for interim extension under this section.

(c) The content of each subsequent interim extension application may be limited to a request for a subsequent interim extension along with a statement that the regulatory review period

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has not been completed along with any materials or information required under §§1.740 and 1.741 that are not present in the preceding interim extension application.

[60 FR 25619, May 12, 1995]

§ 1.791 Termination of interim extension granted prior to regulatory approval of a product for commercial marketing or use.

Any interim extension granted under 35 U.S.C. 156(d)(5) terminates at the end of the 60-day period beginning on the date on which the product involved receives permission for commercial marketing or use. If within that 60-day period the patent owner or its agent files an application for extension under §§1.740 and 1.741 including any additional information required under 35 U.S.C. 156(d)(1) not contained in the application for interim extension, the patent shall be further extended in accordance with the provisions of 35 U.S.C. 156.

[60 FR 25619, May 12, 1995]

Subpart G—Biotechnology Invention Disclosures

DEPOSIT OF BIOLOGICAL MATERIAL

SOURCE: 54 FR 34880, Aug. 22, 1989, unless otherwise noted.

§ 1.801 Biological material.

For the purposes of these regulations pertaining to the deposit of biological material for purposes of patents for inventions under 35 U.S.C. 101, the term biological material shall include material that is capable of self-replication either directly or indirectly. Representative examples include bacteria, fungi including yeast, algae, protozoa, eukaryotic cells, cell lines, hybridomas, plasmids, viruses, plant tissue cells, lichens and seeds. Viruses, vectors, cell organelles and other non-living material existing in and reproducible from a living cell may be deposited by deposit of the host cell capable of reproducing the non-living material.